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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,623	03/10/2004	Edward I. Wulfman	89000.3013NP	6167

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EXAMINER	
WEBB, SARAH K	
ART UNIT	PAPER NUMBER
3731	
MAIL DATE	DELIVERY MODE
05/06/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,623	WULFMAN ET AL.	
	Examiner	Art Unit	
	SARAH WEBB	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,10,17,19,20 and 22-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,10,17,19,20 and 22-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/26/2011 has been entered.

Response to Arguments

2. Applicant's arguments filed 4/26/2011 have been fully considered but they are not persuasive. Upon further consideration of the Nash reference and the claim limitations subsequent to the interview on 4/13/2011, the claim amendments failed to distinguish the claimed invention over the prior art of record. The claims do not specify a cutting head, therefore, the rotatable cutting head is considered to be an integral part of the rotatable torque tube for the purposes of the rejection. Nash discloses another embodiment where fluid exits in a radial direction from a site that is proximal to the distal end of the rotatable torque tube.

3. Although not specifically stated, Nash performs the function of preventing air or other fluids from contacting moveable catheter components in the proximal area of the torque tube. Since the liner surrounds the rotatable torque tube in the housing, other liquids are prevented from contacting its components. Aspirated fluids are directed from

the distal end of the catheter, through the aspiration lumen, and out through the aspiration port.

4. The language *"a catheter…extending distally to enclose the torque tube and the liner"* is a recitation of the relative position of two moveable components. Since the outer catheter (24) of Nash is capable of being moved to a position where its distal end extends beyond the distal end of the atherectomy device (22'), it meets the claim requirements. Nash meets all the claim requirements since the device includes all the claimed components, is capable of being positioned in the claimed manner, and capable of performing the function *"to prevent air or other fluids from contacting moveable catheter components in an area of a proximal end of a torque tube."*

Claim Objections

5. Claim 19 is objected to because of the following informalities: there is a misplaced dash after the word "liner" in line 13. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 2-5, 10, 17, 19, 20, 22-24, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,080,170 (Nash et al.).

Nash discloses an aspiration catheter that includes all the claimed components and is capable of providing a "liquid seal assembly." As shown in Figure 9A, a housing (400 shown in phantom lines) encloses a drive system (322) for a rotatable torque tube, a proximal end of a catheter (24), a proximal end of a stationary liner (22'), an aspiration port (88), and an infusion port (86). Figure 13 shows greater detail of the attachment of the torque tube (308 and 336) to a drive system (turbine 338) within the housing and a sealing site (326) at the proximal end of the stationary liner (34) within the housing. The infusion port (86) is in communication with the flood space between the torque tube (336/308) and liner (34). Although not specifically stated, Nash performs the function of preventing air or other fluids from contacting moveable catheter components in the proximal area of the torque tube.

Figures 10 and 11 show the distal end of the catheter (24) and an atherectomy device 22') disposed within its lumen. As shown in greater detail in Figure 12, the atherectomy device (22') includes a liner (34) surrounding a rotatable torque tube (combination of elements 308, 310, 32") to define a "liquid flood space" between the two tubular components through which fluid is infused. The liner (34) terminates proximally to the distal end (32") of the rotatable torque tube at an intersect area (near 304) that allows fluid to exit the flood space to a location proximal to the distal end of the rotatable torque tube (indicated by arrows transverse to longitudinal axis)(column 21, lines 1-20). Fluids are aspirated through the aspiration lumen that is defined between the outer catheter (24) and the atherectomy catheter (22'), as indicated by arrows (A2) in Figures 10 and 11 (column 16, lines 35-44).

The language *"a catheter…extending distally to enclose the torque tube and the liner"* is a recitation of the relative position of two moveable components. Since the outer catheter (24) of Nash is capable of being moved to a position where its distal end extends beyond the distal end of the atherectomy device (22'), it meets the claim requirements.

Regarding claim 3, Nash describes a helical torque tube (308) that meets the requirement of "coiled drive shaft" and mentions gaps in between the coils (column 23, lines 39-50).

Regarding claim 4, Nash discloses a guide wire (124) used with the system and a guide wire lumen shown passing through the torque tube in Figure 12.

Regarding claim 5, the aspiration port (88) serves as a suction port for removing fluid from the aspiration lumen. The recitation of specific working pressures along the length of the device is not given full patentable weight, as it is a recitation of the intended use of the device. The infusion and aspiration pressures are capable of being adjusted as desired to create a lower pressure in the flood space (column 10) so Nash meets this claim.

Regarding claim 10, the device includes additional ports (such as connection of shaft 336 with bearing 350; ports 24A and B in Figures 10 and 11; port 360 in Figure 13) that are capable of functioning as "overflow ports."

Regarding claims 22 and 23, Nash discloses that the liner (34) has an outside diameter of 1.5mm (0.059 inch) (column 8, line 5) but is silent with respect to its inside diameter and length. It would have been obvious to one of ordinary skill in the art at

the time the invention was made to configure the liner to have an inner diameter of about 0.03 inch to 0.04 inch and a length of about 6 inches, as a mere change in size of a component is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Regarding claim 24, Nash discloses that the liner (34) is made of plastic (column 8, line 3), which is considered to meet the requirements of thin, tough, flexible, and polymer-based tubing.

Regarding claim 26, Nash discloses that the torque tube can be axially translated by moving handle (416) (column 25, lines 27-42).

Regarding claim 27: Although Nash is silent with respect to the selection of the length and diameter of the liner for the purpose of reducing flow rate and requirement for precise diametrical tolerances, it would have been obvious to optimize the relative dimensions of the liner since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nash in view of US Patent No. 6,258,052 (Milo).

Nash forms the liner (34) from a plastic and discloses the use of anti-friction sleeves over components of the system (column 13, line 43), but fails to specify that the liner comprises polyimide tubing with a lubricious coating. Milo teaches that forming a liner over a coiled shaft from a polyimide tube increases pushability and column strength (col. 2, ln. 61 - col. 3, ln. 2). It would have been obvious to one of ordinary skill

to form the Nash liner from a polyimide material with a lubricious coating, as it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH WEBB whose telephone number is (571) 272-5749. The examiner can normally be reached on 9:00am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. W./
Examiner, Art Unit 3731

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3776